UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/737,904	11/20/1996	IRWIN J. GRIFFITH	IMI040CP3	5732

7590 07/01/2003

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON,, MA 02109

EXAMINER
SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/01/2003

47

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/737,904	GRIFFITH ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 and 19-48 is/are pending in the application.

4a) Of the above claim(s) 7,8,16,17,19,20,24,25,29-37 and 42-48 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6,9-15,21-23,26-28 and 38-41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Applicant's election without traverse of Group I and the species LPIX4 and the combination LPIX4, 5, 6, 16, 17, 19, 20 in Paper No. 13 and 19 is acknowledged.

2. Claims 7,8,16,17,19,20,24,25,29-37,42-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13 and 19. Claims 29-36,42 and 43 read on mixtures which are not drawn to the elected species (eg. the combination LPIX4, 5, 6, 16, 17, 19, 20).

3. Claims 1-6,9-15,21-23,26-28,38-41 are under consideration. Claim 18 has been cancelled.

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration (Inventor Kuo's address). See 37 CFR 1.52(c).

5. Drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

6. The use of the trademarks GENEAMP, SEQUENASE, AFFIGEL-10, Q-SEPHAROSE, SUPERDEX 75 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

7. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. If applicant intends to claim priority to the applications disclosed in the declaration filed in the instant application, then applicant needs to amend the specification, page 1, line to recite said applications.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-6,9-15,21-23,26-28,38-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,710,126. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the two sets of claims differ in scope, the elected species of peptides in the instant application are recited in the claims of U.S. Patent No. 5,710,126. Regarding the various functional limitations recited in the claims, said limitations appear to be inherent properties of the specific peptides recited in the claims. Regarding the various manipulations recited in the claims (eg. change sequence to increase solubility), said manipulations are well known in the art (see prior art disclosed in specification, page 12). Therefore, the two sets of claims under consideration in this rejection would have been prima facie obvious in view of each other to one of ordinary skill in the art at the time the invention was made.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-6,9-15,21,23,26-28,38-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed peptides/composition containing said peptides.

Regarding claims 1 and 2, said claims appear to encompass fragments of the peptides recited in the claims wherein the fragment contains a T cell epitope. While the specification discloses that the peptides recited in the claims may contain a T cell epitope, said peptides are 16 or 20 amino acids long. The claim indicates that the T cell epitope can be as small as 7 amino acids. There is no disclosure in the specification of T cell epitopes for the peptides recited in the claims that are smaller than the size of the actual peptide (eg. 16 or 20 amino acids). There is no written description in the specification of the identity of T cell epitopes (as small as 7 amino acids) that are fragments of the peptides recited in the claims. The identity of said epitopes would be determined empirically. Similarly, there is no disclosure in the specification of peptides other than the full length peptides recited in the claims which might have the properties recited in claims 3-6. Regarding claim 9, said claim encompasses any peptide with the functional characteristic recited in the claim irregardless of sequence. There is no disclosure in the specification of such a peptide other than the specific full length peptides recited in claim 1. Regarding claims 10-15, there is no disclosure in the specification of peptides with said functional properties other than the specific peptides recited in claim 1. Regarding claims 26 and 40, there is no written description in the specification of any composition which has been shown to have the functional properties recited in said claim. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred",

Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

12. Claims 21-23,26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not disclose how to use the instant invention for the treatment of disease in vivo in humans. The specification discloses that the claimed peptides can be used for the in vivo treatment of human disease. The substantive real life use for the claimed invention is in vivo treatment of human disease. The specification has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant invention disclosed in the specification is the in vivo treatment of disease in humans. There is no in vitro or in vivo data of any kind demonstrating that the claimed peptides can be used in vivo for the treatment of human disease. The state of the art is such that is unpredictable in the absence of any in vitro or in vivo data (as per the specification) as to whether the method of the instant invention can be used for the treatment of human disease. Hurtenbach et al. teach that peptides are currently unsuitable for therapeutic use (see

page 1503, second column, last two sentences). Hurtenbach et al. teach that peptide administration can provoke "antibody production and severe immunological side effects" (see page 1503, second column).

The specification discloses that several of the claimed peptides stimulate T cell proliferation (eg. see Figures 4 and 5). It is unclear as to how said peptides can be used to treat allergies when said peptides stimulate T cells which mediate said allergies.

Regarding the peptides disclosed in Figure 4, the majority of said peptides appear to be not recognized as antigenic by T cells derived from most Lol allergy patients. There is no guidance in the specification as to how to determine which peptide or combination of peptides can be administered to any particular individual for the treatment of Lol allergy. There is no guidance in the specification as to how much of a particular peptide or peptides needs to be administered to a particular individual in order to treat an allergy. It appears that undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. It appears that undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-6,9,11-15,21-23,26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 appear to intend to read on fragments of the peptides recited in the claims wherein the peptide could be as small as 7 amino acids. Claim 2 indicates that the peptide is 7-10 amino acids in length. However, said claims recite that the peptides are "comprising an amino acid sequence selected from the group consisting of amino acid sequences ..." wherein the recited peptides (eg. LPIX-1, etc) are 16 or 20 amino acids in length. Thus, the peptides recited in the claim (as small as 7 amino acids) are shorter than the size of the peptides actually recited in the claim. This issue

could be addressed by amending the claim (assuming there is support in the specification for such an amendment) to indicate that the peptide is the peptide recited in claim (eg. LPIX-1, etc) or fragment of said peptide.

15. Claims 1 and 2 were amended during prosecution of parent application PCT US94/09024. The amendments do not find support in the specification as originally filed. Therefore, regarding the application of prior art and claims 1-6,9,12-15,21-23,26-28, priority is not extended to the parent applications to which priority is claimed in the declaration of the instant application and the priority date is the filing date of the instant application (eg. 08/737904).

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 1-6,9,12-15,21-23,26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffith et al. (WO 95/06728).

Claims 1-6,9, 12-15,21-23,26-28 of Griffith et al. disclose peptides encompassed by the claimed inventions. Griffith et al. contains originally filed claims 1 and 2 of said PCT application (eg. before they were amended).

18. Claims 1,3-5,12-15,21,23,26-28,38-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Singh et al. (US Patent 5,721,119).

Singh et al teach the amino acid sequence of Lol p Ib.1 (see SEQ. ID. no. 1) wherein said sequence contains LPIX-4. Singh et al. teach three 13mer peptides that each contain 13 overlapping amino acids derived from LPIX-4 (see TABLE 4). Said

peptides would contain a T cell epitope because they are larger than 7 amino acids and overlap almost the entire LPIX-4 molecule. The specification of the instant application does not disclose what fragments of LPIX-4 would have the functional characteristics of claims 3-5, but said properties would be an inherent property of the fragments. Since the peptides of Griffith et al. overlap almost the entire LPIX-4 molecule they would be expected to have the properties of T cell epitope possessing fragments of said peptide. Singh et al. teach that the peptides can be modified to improve solubility (see column 145, second paragraph). Singh et al. teach that such peptides can be modified to not bind IgE (se column 9, second paragraph). Singh et al. teach that said peptide can modified with the functional property recited in claim 15 (see column 10, first incomplete paragraph). Regarding claims 9-11, 38-41, Table 4 represents 34 different peptides derived from Lol p Ib.1 (AKA Lol p V), so it would be reasonable to conclude that at least some of said peptides had the functional attributes recited in said claims. Singh et al. teach a composition containing said peptide and a pharmaceutically acceptable carrier (see column 24). Singh et al. teach the composition of claim 26 (see column 24, second paragraph).

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 1-6,9-15,21-23,26-28,38-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. in view of Perez et al.

Singh et al teach the amino acid sequence of Lol p Ib.1 (see SEQ. ID. no. 1) wherein said sequence contains LPIX-4. Singh et al. teach three 13mer peptides that each contain 13 overlapping amino acids derived from LPIX-4 (see TABLE 4). Said peptides would contain a T cell epitope because they are larger than 7 amino acids and overlap almost the entire LPIX-4 molecule. The specification of the instant application does not disclose what fragments of LPIX-4 would have the functional characteristics of claims 3-5, but said properties would presumably be found in at least some of said fragments. Since the peptides of Griffith et al. overlap almost the entire LPIX-4 molecule they would be expected to have the properties of T cell epitope possessing fragments of said peptide. Singh et al. teach that the peptides can be modified to improve solubility (see column 145, second paragraph). Singh et al. teach that such peptides can be modified to not bind IgE (se column 9, second paragraph). Singh et al. teach that said peptide can modified with the functional property recited in claim 15 (see column 10, first incomplete paragraph). Regarding claims 9-11, 38-41, Table 4 represents 34 different peptides derived from Lol p Ib.1 (AKA Lol p V), so it would be reasonable to conclude that at least some of said peptides had the functional attributes recited in said claims. Singh et al. teach a composition containing said peptide and a pharmaceutically acceptable carrier (see column 24). Singh et al. teach the composition of claim 26 (see column 24, second paragraph). Singh et al. do not teach the peptides of claims 2,6,22 or a peptide identical in length to LPIX-4. Perez et al. teach that a collection of 20mer peptides can be made from a different rye grass allergen (Lol p I) in order to determine which portions of the molecule contain T cell epitopes (see page 16212, second column. last paragraph, continued on next page). The peptides are 20mers made starting with the first amino acid of the allergen wherein the following 20mer overlaps by 10 amino acids. The peptides in the instant application (including LPIX-4 and the particular combination of LPIX peptides elected by applicant) were made using the same strategy with a different Lol antigen. A routineer would have used the strategy taught by Perez et al. in order to produce a collection of peptides to identify the T cell epitopes. Singh et al. teach that it is desirable to identify the T cell epitopes of Lol p Ib and that this information would be ascertained by screening fragments for reactivity with T cells (see columns 9 and 10). Smaller fragments of the 20mer peptides would have been made to identify the minimal T cell epitope present, which the art recognizes

to be in the 7-10 amino acid length. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Singh et al teach the amino acid sequence of Lol p Ib.1 (see SEQ. ID. no. 1) wherein said sequence contains LPIX-4 and the other LPIX peptides present in the combination elected by applicant whilst Perez et al. teach that a collection of 20mer peptides can be made from a rye grass allergen in order to determine which portions of the molecule contain T cell epitopes. Smaller peptides of the size 7-10 amino acids would have been made to determine the minimal T cell epitope. One of ordinary skill in the art would have been motivated to do the aforementioned because a routineer would have used the strategy taught by Perez et al. in order to produce a collection of peptides to identify the T cell epitopes in of Lol p Ib.1, whilst Singh et al. teach that it is desirable to identify the T cell epitopes of Lol p Ib.1, and that this information would be ascertained by screening fragments for reactivity with T cells. A routineer would have produced mixtures of various combinations of the 20mer peptides because Singh et al. teach use of mixtures of peptides in vivo (see column 12) and various mixtures of peptides would have been produced to establish what mixture functioned best in vivo

21. No claimed is allowed.

22. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800
1644

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.